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The American Foundation for the Blind is pleased to have the opportunity to submit comments to the FDA for the *Medicare Prescription Drug Improvement and Modernization Act of 2003: Study on Making Prescription pharmaceutical Information Accessible for Blind and Visually Impaired Individuals.* AFB is providing information in response to the following requests:

- Information About the Population of Interest
- Information About the Use of Prescription Medication Information by this population
- Information About Emerging and Existing Technologies

The mission of the American Foundation for the Blind is to enable persons who are blind or visually impaired to achieve equality of access and opportunity in all aspects of society. AFB accomplishes this mission, in part, by taking a national leadership role in the development and implementation of public policy and legislation.

These comments were prepared by the Governmental Relations Department in collaboration with the staff of AFB's National Aging Program, National Literacy Center, Technology and Employment Center, and Department of Policy Research and Program Evaluation.

We commend the FDA for the comprehensive outline of questions provided to assist public comment. When used correctly, prescribed medications have the potential of greatly improving the health and independence of older individuals who are blind or visually impaired. However, as we point out in detailed responses to these questions, older individuals who are blind or visually impaired face severe and sometimes dangerous challenges in managing their medication.

Respectfully submitted,

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SUMMARY STATEMENT

Estimates, taken from federal surveys, of the prevalence rates and numbers of vision impairment (including blindness) vary greatly. However, those surveys reveal quite consistent *relationships* of visual impairment with socioeconomic, demographic and health characteristics. Visual impairment is associated with older age, lower educational and economic levels, multiple impairments, and poor health. Taken together, those characteristics have a generally negative affect on the population of interest's health literacy and adaptive learning capabilities necessary to access prescription information. Other types of impairment associated with visual impairment, notably hearing loss, further complicate access to this information.

Organized data regarding inappropriate use of medication while the medication is in the control of the consumer are lacking because neither of the national medication error reporting programs has specific codes related to blindness and vision impairment. Because strong anecdotal information does exist regarding medication error, we ask that the FDA provide immediate attention to development and use of such codes.

Technology which can access the full range of information necessary to effectively manage medication is available, but only at high cost to the consumer. Outside of the programs of the Department of Veterans Affairs, no third-party reimbursement is available for any of these devices. Limited-use technology such as a "talking" prescription bottle is available at little or not cost. At present, few of these devices have had the benefit of study to determine their impact in reducing prescription error.

RESPONSES TO SECTION A, "INFORMATION ABOUT THE POPULATION OF INTEREST"

Prevalence Estimates and Data Sources

[Note: Because FDA's study is focused on Medicare, the population of interest is predominantly the elderly population, 65 years and older. Of course, Medicare covers persons under age 65 who qualify on the basis of disability; thus we refer to data sources that include the broader group.]

Several federal surveys inquire about respondent's visual status, along with demographic variables and health-related information relevant to FDA's study on making prescription pharmaceutical information accessible to the visually impaired population. [Note: for brevity, referred to as "prescribed drug" below].

Before listing those surveys as data sources, and then presenting some findings that help to answer FDA's study questions, we must point out a serious barrier to estimating the "scope of the problem" in terms of the prevalence of vision impairment. The barrier is that every one of the relevant federal surveys asks about visual impairment in a different way. Not surprisingly, therefore, the resulting estimates of prevalence of visual impairment vary so widely as to be of questionable utility.

Estimates of the number of people with difficulty seeing (even when using one's usual eyeglasses), in the U.S. non-institutionalized population, range from as low as 7 million to as high as 20 million people (all ages). There is greater consistency in estimates of the number of people with very severe visual impairment, i.e., cannot see at all, or almost not at all; the latter group is estimated as approximately 1.5 million to 2 million people. Of course, the target population for FDA's study should not be limited to that most severely impaired group. That is because high potential for error in managing one's prescribed drugs applies to people who have *difficulty seeing*, as well as those who *cannot see*, although the solutions for avoiding such error in self-care will be different for those sub-groups based on severity of vision impairment.

Best corrected" versus "usual correction: The surveys referred to above (and below) use self-reports of people's functional visual ability with their usual eyeglasses ("usual correction"), or with no eyeglasses if they are not usually worn. In other words, such surveys reflect the usual circumstances in which people manage their prescribed drugs. Part of that reality is economic, keeping many people from using optimal vision correction. This reality contrasts with recent epidemiological data published in the *Archives of Ophthalmology,* under National Eye Institute auspices.

That report estimates that about 3.4 million Americans are visually impaired (20/40 or worse acuity, including blind), but it employs a clinical measure by which people in the sample use the best possible correction of their vision, and are assessed under optimal testing conditions, e.g., good lighting, lack of clutter, concentration on the visual task, etc. In other words, the clinical criteria are not relevant for FDA's study because they do not reflect the usual conditions under which people use vision (or alternatives to vision) for managing their medications.

Relevant Federal Surveys [and the agencies responsible for them]: The following listing shows whether each survey is conducted on a recurrent basis, thus indicating its potential as a source for estimating *trends* in the prevalence of visual impairment by age group. Recurrent studies also may offer potential for future inclusion of survey items by the FDA designed to answer questions in its current study that must go unanswered with existing data. (See "Long-range and short-run research..." below).

1) National Health Interview Survey (NHIS) [National Center for Health Statistics, NCHS, of the Centers for Disease Control and Prevention - CDC], conducted annually. For the two-year period, 1994-95, NHIS added a one-time "Disability Supplement" (NHIS-D), which is a particularly useful source for certain items; of all the surveys, it is the only one that asked about "legal blindness."

2) Survey of Income and Program Participation (SIPP) [Bureau of the Census], conducted annually, however, the question about visual impairment is included only periodically. The following surveys also provide periodic data on vision impairment:

3) Medical Expenditure Panel Survey (MEPS) [Agency for Healthcare Research and Quality AHRQ],

4) Medicare Current Beneficiary Survey (MCBS) [Centers for Medicare and Medicaid Services, CMS].

Long-range and short-run research to answer FDA's questions: For future research on prescribed drug management, as well as an array of other health care issues faced by people with visual impairment, it is critical that work be undertaken to standardize the survey measures that identify that target population. Of course, methodological work is necessary first to determine which measure(s) should be promoted as the standard. That is the long-range task.

For the short run, a focused analysis of the listed surveys, including a methodological review of the vision items, would have a meaningful pay-off to answer FDA's questions in its current

study. The proposed study [lasting 6 months – 1 year] would provide useful data on health service utilization patterns, including prescribed drug use, by the population of interest, and detailed data on their relevant socio-demographic characteristics. It could yield a solid basis for projecting the costs and benefits of alternative solutions to the problem of safely and effectively managing prescribed drugs, with blindness or visual impairment. Thus, such analysis could answer the FDA's questions more reliably and with more explanatory power than is currently possible.

Socio-economic, Demographic and Health Status Patterns. - In spite of wide variation in estimates of the *size* of the population of interest, the studies consistently find certain *relationships.* The following associations of visual impairment and other individual characteristics are clear and relevant.

(1) Aging: the rate of visual impairment increases with aging, e.g., the rate is higher in each older cohort. This finding also means that most people (in the U.S.) who are elderly and visually impaired acquired the impairment recently, as they aged. A small subgroup, of course, became visually impaired at birth or in youth and then became aged; that small subgroup is more aware of and adept at using alternatives to visual information than is true of the vast majority of their visually impaired peers.

(2) Severity of Vision Loss: By far most people with visual impairment have some ability to see, although it is more or less severely limited, even wearing glasses. Even the group mentioned above, estimated as 1.5 – 2.0 million most severely visually impaired, includes many with slight ability to see. The "totally blind" population is estimated at well under 500,000.

(3) Multiple impairments: most people with visual impairment (i.e., two-thirds or more) also have one or more other impairments that must be considered in selecting solutions to problems with using visual information about prescribed drugs, e.g., hearing impairment and/or limited dexterity. Furthermore, the rate of multiple impairments of which visual impairment is one, increases with aging.

(4) Health status: It is important to distinguish between "impairment" and "general health." Indeed, the public health goal for the nation is for people with impairments, visual or other, to maintain good health. Nevertheless, studies show that people with visual and other impairments have poorer health than the general population, and thus have greater need for prescription drugs.

5) Economic resources: the rate of visual impairment decreases with higher family income, e.g., rates are highest among people in poverty, and conversely, people with visual impairment are likely to be financially constrained

6) Educational attainment: Mainly because of the older age of the visually impaired population, it has substantially lower educational attainment than the general population. Among people 65 and older, each younger cohort has a higher percentage who have completed high school (i.e., people who are 90+ have lower educational attainment than those in their 80s,

etc.), a pattern that applies to the general population. However, because of the association of poverty and impairment, the education difference between the visually impaired and general population persists even in younger cohorts. Education, of course, has a direct relationship to health literacy, as well as access to and training in computer and other technologies used as alternatives to print.

The following are some additional findings from various sources, shared as preliminary and rough estimates, for purposes of FDA's current study. The proposed short-term focused review of the listed surveys would allow more certainty around these and similar statements.

- As an approximate mid-point estimate in the range of prevalence estimates: About one in six, or 6.5 million Americans age 55 and older, report vision loss even with usual glasses. This number is expected to double by 2030 as baby boomers age and the older population climbs to 78 million or about 20% of the overall population.
- Four of the five major causes of blindness and vision impairment are primarily related to aging: macular degeneration, cataracts, glaucoma, and diabetic retinopathy.
- According to the National Eye Institute, glaucoma rates are dramatically higher for the population who are African-American or Hispanic than among Whites.

The FDA study asks specifically about prevalence of hearing loss and other "co morbidities." (See above re "multiple impairments.") NHIS-D shows that the rate of multiple impairments steadily increases with age, such that virtually everybody 90 years or older who is visually impaired reports other impairments. It also shows that about 30% of people 65 and older who are visually impaired, report hearing impairment. Another source of information on co-morbidities is an analysis of program participants in the only federally-funded program serving older blind individuals (Title VII-Chapter 2, "Independent Living Services for Older Individuals Who are Blind," Rehabilitation Act of 1973, as amended). Note that "Chapter 2" participants are not a representative sample of the nation. A report of 2002 data from Chapter 2, prepared by the Mississippi State University's Rehabilitation Research & Training Center on Blindness and Low vision found, in descending order of prevalence, the following conditions: cardiovascular, muscular/skeletal, diabetes, and hearing loss.

Health Literacy and Adaptive Learning Capabilities

Technology has significant potential for assisting older individuals who are blind or visually impaired to more effectively and safely manage their medications. AFB's Technology and Employment Center's extensive experience in evaluating assistive technology provides clear evidence that *access* to the information is not the same as *learning* the information. Simply providing the technology without recognizing the training needs and learning skills of an older individual, almost guarantees that the device will go unused.

The National Library of Medicine defines health literacy as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions." The National Adult Literacy Survey (NALS) of 1993, indicates the potential for a serious problem. It found that 75% of American adults who

reported having an impairing health condition scored in the two lowest literacy levels. (Note: Data from the 2003 survey will be available for analysis soon; we recommend they be examined as part of this study.) Two difficulties with NALS concern us for the current purpose. First, visual impairment was asked in yet another way, compared to the other federal surveys; second, no questions documented use of optical aids, screen readers, or non optical aids such as reading stands and writing guides. We cannot be sure that those reporting vision impairment scored lower on the tests of literacy because they did not have adaptive aids. If they did have them, we do not know that they were able to use them efficiently.

Clearly, the impact of vision loss on document literacy is greater if consumers also have difficulty using assistive technology, compounding their difficulty understanding printed prescription material which often contains charts, graphs, and tables.

We strongly urge the FDA to consider developing a comprehensive study that explores more fully the relationships among literacy, visual impairment, and managing one's health care safely and effectively.

RESPONSE TO SECTION B, "INFORMATION ABOUT THE USE OF PRESCRIPTION MEDICATION INFORMATION BY PEOPLE WHO ARE BLIND OR VISUALLY IMPAIRED"

AFB has discussed this issue in detail with U.S. Pharmacopeia. We understand that they will file in response to this docket. Unfortunately neither of the two USP medication error reporting programs, USP-ISMP Medication Errors Reporting (MER) Program and MEDMARX, has codes specific to blindness or visual impairment. We understand that USP is sharing some reports which have been generated by general text-querying methods which produced 13 reports from the MER program and four reports from MEDMARX.

As stated in our summary, there is anecdotal evidence which, taken in combination with the MER and MEDMARX findings, indicates the necessity of addressing the problem of data collection regarding medication error as it relates to blindness and vision impairment. For example, Drug Topics of February 23, 2004 published by Advanstar Medical Economics Healthcare Communications reports that the Institute for Safe Medication Practices now considers insulin a high alert medication – one requiring special handling to insure its safe use. Good safe use practices should include accentuation of differences between look-alike products, safe storage, and stickers to call attention to important but easily missed information. These safe handling suggestions require visual access to the information.

The report also notes that "Experts are concerned that the problem may get worse. The American Diabetes Association estimates that as the population continues to age, more people will develop diabetes, causing insulin use to increase 26% in Type 2 diabetes patients and 10% among those with type I by the year 2006." We add our concern that concomitant incidence of diabetic retinopathy will increase the need for accessible medication information along with accessible health monitoring equipment.

Our concern over the lack of reliable data was increased after examining the findings in the "Since You Care" guides jointly published by the National Alliance for Caregiving and MetLlife. "Older Americans are hospitalized six times more than the general population due to adverse drug reactions." The guides also state the following: "Studies have shown that fewer than 30% of older adults take their medication properly."

Because a wide array of issues affects proper use of prescription drugs, we do not assume that the error rate is entirely due to blindness or vision impairment. However, the association of aging, vision loss, and high needs for health care including medication is well-established and needs to be examined more closely.

The FDA study also asks how people who are blind or visually impaired currently get their prescription drug information. We asked the Directors of the above captioned Chapter 2 programs to help us respond. We provide the bullet items as a summary of responses.

- Friends and/or family members read the medication bottle information or the pharmacist may read the information to them.
- They try to memorize the shape of the pill as it feels in their hands because the print is too small and the bottles are the same size.
- Those with remaining vision use extra task lighting and some use magnifiers.
- Those living alone must often rely on the memory, reading skills, and good graces of the next visitor to help them if they become confused by the passage of time and the need to memorize other information.
- A few use so-called talking pill bottles which identify medication and related prescription information. These devices are not usable for individuals with hearing impairment.
- Patients who are diabetic do not have reliable or wide spread access to health monitoring equipment such as blood glucose monitoring systems needed to alert them to insulin requirements.

Clearly, fall-back on such approaches creates the potential for serious error.

RESPONSE TO SECTION C, "INFORMATION ABOUT EXISTING OR EMERGING TECHNOLOGIES"

We combine our response regarding existing and emerging technologies with a response to the Section B question regarding effective communication of essential drug information. Currently available accommodations capable of providing prescription information range from low-end, low-cost items like bold line or raised line paper for note taking, and high-intensity lamps to higher cost video magnification equipment and to the highest end of the cost scale, personal digital assistants with Braille input/output, and specialized speech output software for computers. We direct the FDA to http://www.afb.org/Section.asp?SectionID=4&TopicID=31 for complete explanations and price ranges for such equipment.

Effective communication of essential prescription information is dependent on significant variables like remaining useful vision, educational attainment, and availability of appropriate training in the use of technology. Anecdotal evidence from the Chapter 2 program shows that, when proper instruction is available, older individuals who are blind or visually impaired effectively used remaining vision to use some of this equipment. Much of the available assistive technology which could be used for the purposes described in the study has been evaluated by AFB's technical experts at the AFB TECH Product Evaluation Laboratory. These objective evaluations have involved testing of product performance and ease of use for reading tasks undertaken by a younger population than targeted by the FDA study. AFB would look forward to performing evaluations more targeted to the study population.

Before examining available technology, its utility for medication management, and sources of reimbursement, it is necessary to have a greater understanding of the tasks which a blind or vision-impaired person must master in order to manage proper use of prescription drugs. The FDA's own Center for Drug Evaluation and Research provides a good sense of the comprehensive range of information necessary for effective prescription drug management. Almost every one of these elements pertains to access to printed information. As we read "Medicines and You: A Guide for Older Adults" it became apparent that older individuals need more information than is on the prescription container.

Single Purpose Devices

Hand-held magnifiers, plastic pill organizers, and alarms can help. These items are typically very low cost. However, individuals with vision impairment require training in use of remaining vision to use such devices.

Moving toward the higher end of such devices, some pill organizers also have a record feature so that an individual or a health care provider can record memos with specific information about each medication. There are other tools on the market which employ bar codes and hand-held scanners to label and identify items, and others which can record memos that correspond to bar codes placed on the items. Although these approaches can improve access, they rely on the user or health care provider to create the proper memo for every medication, adding further potential for error.

Other products use similar scanning technology. However, the labels are created by the pharmacy when the medication is purchased which does reduce the potential for user error in labeling. The pharmacy must have the software to produce the labels.

Multi-Purpose Information Access

One of the more commonly available devices, the closed-circuit television (CCTV) may have significant utility for accessing prescription drug information. CCTVs use a stand-mounted or handheld video camera to project a magnified image onto a video monitor, a TV screen, or a computer monitor. Such devices range in price from $400 to $1,000 for those that plug into a TV to $1,800 to $4,000 for stand alone devices.

Optical character recognition (OCR) devices provide more versatility. Initially, a printed document is scanned by a camera. OCR software then converts the images into recognized characters and words. A synthesizer in the OCR system than speaks the recognized text. Finally, the information may be stored in a personal computer or the memory of the OCR system itself. In some OCR systems these files can be converted into other formats retrievable by commonly used software. The user can also access the scanned text by using adaptive technology devices that magnify the computer screen or provide speech or Braille output. Self contained OCR systems or those that are bundled with a PC are in the $4,000 to $5,500 price range.

At the highest end, there are currently available several competitive products using Braille and standard typewriter keyboard input which function in a fashion similar to a personal digital assistant. These have highly useful functions for note taking and task management which can be essential for effective medication management. However, they range in price from $1,400 to over $5,000 and require significant training and advanced personal computer management skills.

A significant emerging technology is based on a new specification for digital talking books developed through the Digital Audio-based Information System consortium which would allow content to be delivered on a CD-ROM for reading in specially designed players, repurposed into Braille and large print, accessed over the Internet, or even through a touch-tone telephone. The great attractiveness of this technology is that it can be deployed via the telephone which does not require complicated instructions and experience in use. In addition this technology can provide important privacy protections.

There are three drawbacks for all high-end multi-purpose access devices. The first is expense. Outside of the Veterans Administration programs and limited low-tech purchases for clients of the Chapter 2 program, there is no third party reimbursement from government or private insurers. This may be a small factor in the purchase of very low end products because they are simply not very expensive. It is certainly a factor for the above referenced devices which can cost a consumer from several hundred to several thousands of dollars The second drawback is very significant. There is a general lack of awareness of the existence of these products by both blind and visually impaired older persons and their health care providers. Finally, while some of the high end devices have great utility for displaying, storing and managing prescription drug information, they are complex devices and effective use depends on a high degree of literacy.

In conclusion, we commend the FDA for this comprehensive set of questions. However, AFB believes that further study is needed before actionable conclusions can be made with regard to prevention of error and the potential for assistive technology to provide a basis for reliable management of prescription drug information.